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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

HM22/0518

SPECTOR, L

ART UNIT	PAPER NUMBER
1647	9

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DATE MAILED: 05/18/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-45 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1996-409-290/40029

Part III: Detailed Office Action

Notice: **Effective June 18, 2000**, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to peptides, classified in class 530, subclass 350.

II. Claims 3-32, drawn to peptides of the formula $R1_xR2_yR3_z$ and nucleic acids encoding such, classified in class 435, subclass 69.7.

III. Claims 33-36, drawn to antibodies, classified in class 530, subclass 387.9.

IV. Claim 37, drawn to a genetic diagnostic method, classified in class 435, subclass 6.

V. Claims 38 and 39, drawn to a method of stimulating growth or activating PDGFα-R using the protein of claim 17, classified in class 514, subclass 2.

VI. Claim 40, drawn to a method of inhibiting PDGFα-R using the protein of claim 17, classified in class 514, subclass 2.

VII. Claims 41 and 42, drawn to a method of inhibiting zvegf3 activity using antibodies, classified in class 424, subclass 130.1.

VIII. Claims 41 and 42, drawn to a method of inhibiting zvegf3 activity using a receptor of receptor fragment, classified in class 514, subclass 2.

IX. Claims 41 and 42, drawn to a method of inhibiting zvegf3 activity using a fusion protein, classified in class 424, subclass 134.1.

X. Claims 43-45, drawn to antisense nucleic acids and use thereof as expression inhibitors, classified in class 514, subclass 44.

The inventions are distinct, each from the other because:

Inventions I and II are drawn to physically, functionally and patentably distinct products wherein each product does not require the others, the products have different uses and means of manufacture, and the products require non-coextensive searches. The epitope bearing peptides of Invention I do not require the conserved motifs of Invention II, and the two groups require separate searches. Accordingly, restriction is proper.

The proteins of Inventions I and II are related to the antibodies of Invention III by virtue of comprising the cognate antigen, and thus being useful for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the receptor protein.

The products of Inventions I-III are separate and distinct from the methods of Invention IV wherein the products may neither be made by nor used in the methods. Accordingly, restriction is proper.

The products of Invention I are separate and distinct from the methods of Inventions V-X wherein the products may not be made by the methods and are not required to carry out the methods. Accordingly, restriction is proper.

Inventions II and each of Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in either of the patentably distinct methods, or as an antigen for the production of the antibodies of Invention III.

The proteins of Invention II are separate and distinct from the methods of Invention VII-X, and the nucleic acids of Invention II are separate and distinct from the methods of Inventions VII-IX, wherein the products may neither be made by nor used in the methods. Accordingly, restriction is

proper.

Some of the antisense oligonucleotides of Invention X are related to the nucleic acids of Invention II by virtue of being subsequences of longer disclosed sequences. However, these inventions are patentably distinct both because the nucleic acids of Invention II are not required for Invention X, and because they are used in materially different processes which processes are completely different and distinct. The arts of antisense therapy and recombinant production of proteins are separate and distinct, and require non-coextensive searches. Accordingly, restriction is proper.

The products of Invention III are separate and distinct from the methods of Invention V-X wherein the products may neither be made by nor used in the methods. Accordingly, restriction is proper.

The products of Invention X are separate and distinct from the methods of Invention V-IX wherein the products may neither be made by nor used in the methods. Accordingly, restriction is proper.

The various methods Inventions IV-X are drawn to patentably distinct methods. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

The methods of Invention IV are separate and distinct from all the other methods, as they use different active agents and method steps, and require different outcomes and non-coextensive searches. The methods of Inventions V and VI use two mutually exclusive sets of active agents for opposite purposes. Inventions V and VI are distinct from inventions VII-X because different active agents are used for different purposes, and the various methods require non-coextensive searches. The methods of Inventions VII-IX, although sharing the common outcome of inhibiting zvegf3 activity, utilize different active agents, and thus require non-coextensive searches. Finally, the methods of invention X utilize active agents and method steps not required for any of the other methods, and require a non-coextensive search compared with that for any of the other methods.

Therefore, a search and examination of all Invention V-X's methods in one patent application would result in an undue burden, since the searches for the Inventions' methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species:

In addition to the above Restriction requirement, a further election of species is required as follows:

- If applicants elect Invention I:

This application contains claims directed to the following patentably distinct species of the claimed invention: each of the specific fragments recited in claim 2 constitutes an individual species, for a total of 13 separate species. Each fragment is considered to constitute a patentably distinct species because they have separate structure, and require separate searches. Search of more than a single amino acid sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- If applicant elects any one of Inventions II, III, V or VI:

This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 3 encompasses innumerable distinct species, each of which has a different sequence, and requires a separate search. Applicants are required to designate a single, ultimate species to be searched, including designation of (a) whether the elected species is a single chain, a homo- or hetero-dimer, (b) the identity of the first polypeptide, (c) the identity of the second polypeptide, and (d) values for each of x, y and z.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3, 15, 16, 17, 25-26, 28-36, and 38-40 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information:

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 37 C.F.R. § 1.48(b) and by the fee required under 37 37 C.F.R. § 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

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